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| WILSON SONSINI GOODRICH & ROSATI | | | COBANOGLU, DILEK B | |
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| PALO ALTO, CA 94304-1050 | | | PAPER NUMBER | |
| | | | 3626 | |

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/881,181 | WALLACH ET AL. | |
| | Examiner | Art Unit | |
| | Dilek B. Cobanoglu | 3626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>04/28/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 04/28/2006. Claims 1-4, 7, 19-20, 22-23, 25, 29-32 and 35 have been amended. Claims 1-57 continue pending.

Specification

2. The substitute Abstract has been received and accepted. The objection has been withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6, 10-22, 26-35, 37-40, 42-50, 52-57 are rejected under 35

U.S.C. 102(e) as being unpatentable by Sparks (U.S. Patent Publication No.

2001/0037215 A1).

A. As per claim 1, Sparks discloses a method for securely collecting information from a user, comprising:

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- a. Delivering a medical test device to a patient (Sparks; par. 0033, 0037 and Fig. 1),
- b. Retrieving test data from the test device after use by a patient (Sparks; par. 0038); and
- c. Distributing test data to authorized recipient (Sparks; par. 0037 and 0042).

B. As per claim 2, Sparks discloses the method of claim 1 wherein the test device has a data collector comprised of a hardware device (Sparks; par. 0059 and 0062).

C. As per claim 3, Sparks discloses the method of claim 1 wherein said step (b) comprises retrieving a data collector from the test device and extracting the data (Sparks; par. 0038 and 0059).

D. As per claim 4, Sparks discloses the method of claim 1 wherein said step (b) comprises extracting the data before retrieving a data collector from the test device (Sparks; par. 0038).

E. As per claim 5, Sparks discloses the method of claim 1 wherein said step (a) comprises:

- a. 1) accepting a request to ship a test device from a requestor (Sparks; par. 0015); and
- a. 2) communicating with a logistics system directing shipment of the device to the patient (Sparks; par. 0076).

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F. As per claim 6, Sparks discloses the method of claim 5 wherein said step (a) 1) comprises the sub-steps of: authorizing the requestor to make the request; and accepting the request (Sparks; par. 0042).

G. As per claim 10, Sparks discloses the method of claim 4 wherein at least a portion of said step (a) is performed via a computer over a communications network (Sparks; par. 0039).

H. As per claim 11, Sparks discloses the method of claim 10 wherein said communications network includes a modem (Sparks; par. 0018).

Examiner considers that since the system disclosed by Sparks includes a modem since it includes communication types such as phone, fax, and e-mail and online.

I. As per claim 12, Sparks discloses the method of claim 10 wherein said communications network is a global computer communications network (Sparks; par. 0039).

J. As per claim 13, Sparks discloses the method of claim 11 wherein said communications network is a wireless link (Sparks; par. 0039).

K. As per claim 14, Sparks discloses the method of claim 1 wherein said step (c) is performed over a series of at least one private and at least one public network (Sparks; par. 0039).

L. As per claim 15, Sparks discloses the method of claim 1 wherein said step (c) comprises:

- c. 1) determining, based on input from the patient, said authorized recipient (Sparks; par. 0042) and ;
- c. 2) verifying a recipient's authorization to receive data before distributing said data (Sparks; par. 0042).

M. As per claim 16, Sparks discloses the method of claim 1 wherein said step (c) is performed using secure communications (Sparks; par. 0042).

N. As per claim 17, Sparks discloses the method of claim 4 wherein said step (b) is performed using secure communications (Sparks; par. 0042).

O. As per claim 18, Sparks discloses the method of claim 1 wherein step (a) comprises the sub-steps of:

- a. 1) receiving a request from a first physician for a medical test, subject to verification by an authorized physician (Sparks; par. 0016, 0017)
- a. 2) receiving authorization from the authorized physician (Sparks; par. 0042).

P. As per claim 19, Sparks discloses the method of claim 18 wherein step (c) comprises:

- c. 1) receiving authorization from the patient for the first physician to receive distributions of patient's data (Sparks; par. col. 0016, 0017 and 0038); and
- c. 2) distributing the patient's data to the first physician (Sparks; par. 0042).

Q. As per claim 20, Sparks discloses a method for collecting data, comprising:

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- a. Providing a testing apparatus to a patient in response to a request for the testing apparatus; (Sparks; par. 0016 and 0033)
- b. Administering a medical test to the patient with the testing apparatus; (Sparks; par. 0035, 0036 and Fig.1)
- c. Collecting the testing apparatus from the patient once the patient completes the testing (Sparks; par. 0037 and 0061); and
- d. Distributing test information from the testing apparatus to authorized recipients (Sparks; par. 0038 and 0042).

R. As per claim 21, Sparks discloses the method of claim 20 wherein said step (a) comprises:

- (a1) accepting a request to ship a test device from a requestor (Sparks; par. 0017); and
- (a2) communicating with a logistics system directing shipment of the device to the patient (Sparks; par. 0076).

S. As per claim 22, Sparks discloses the method of claim 21 wherein said step (a1) comprises the sub-steps of: authorizing the requestor to make the request; and accepting the request (Sparks; par. 0042).

T. As per claim 26, Sparks discloses the method of claim 20 wherein said step (a) is performed via a computer over a communications network (Sparks; par. 0090).

U. As per claim 27, Sparks discloses the method of claim 26 wherein said communications network is a modem (Sparks; par. 0018).

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Examiner considers that since the system disclosed by Sparks includes a modem since it includes communication types such as phone, fax, and e-mail and online.

V. As per claim 28, Sparks discloses the method of claim 26 wherein said communications network is a global computer communications network. (Sparks; par. 0039).

W. As per claim 29, Sparks discloses the method of claim 26 wherein said communications network is a wireless link (Sparks; par. 0039).

X. As per claim 30, Sparks discloses the method of claim 20 wherein said step (d) is performed over a series of at least one private and one public network (Sparks; par. 0039).

Y. As per claim 31, Sparks discloses the method of claim 20 wherein said step (d) comprises: (d1) determining, based on input from the patient, said authorized recipient; and (d2) verifying a recipient's authorization to receive data before distributing said data (Sparks; par. 0042).

Z. As per claim 32, Sparks discloses the method of claim 20 wherein said step (d) is performed using secure communications (Sparks; par. 0071).

AA. As per claim 33, Sparks discloses the method of claim 20 wherein said step (a) is performed using secure communications (Sparks; par. 0040).

BB. As per claim 34, Sparks discloses the method of claim 20 wherein step (a) comprises the sub-steps of: (a1) receiving a request from a referring physician for a medical test, subject to verification by an authorized physician; and (a2)

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receiving authorization from the authorized physician (Sparks; par. 0016 and 0077).

CC. As per claim 35, Sparks discloses the method of claim 34 wherein said step (d) comprises: (d1) receiving authorization from the patient for the referring physician to receive distributions of patient's data; and (d2) distributing the patient's data to referring physician (Sparks; par. 0038).

DD. As per claim 37, Sparks discloses the method of claim 36 wherein said steps are performed sequentially (Sparks; par. 0087).

EE. As per claim 38, Sparks discloses the method of claim 36 wherein said step (a) is performed using an information server coupled to a public network (Sparks; par. 0039).

FF. As per claim 39, Sparks discloses the method of claim 36 wherein said step (a) comprises:

(a1) accepting a request to ship a medical test device from the physician (Sparks; paragraph 17).; and

(a2) communicating with a shipper directing shipment to the patient (Sparks; paragraph 78).

GG. As per claim 40, Sparks discloses the method of claim 39 wherein said step (a1) comprises the sub-steps of: verifying the physician is authorized to make the request; and accepting the request (Sparks; par. 0042).

HH. As per claim 42, Sparks discloses the system of claim 41 wherein the interface server includes an order authorization application (Sparks; par. 0042).

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II. As per claim 43, Sparks discloses the system of claim 42 wherein the authorization application includes at least a consumer access level, a patient access level, a member access level and a physician access level (Sparks; par. 0041).

JJ. As per claim 44, Sparks discloses the system of claim 41 wherein the database server includes a data structure including a physician record data structure (Sparks; par. 0038), a manufacturing record database (Sparks; par. 0076), a client record database (Sparks; par. 0075) and a device record data structure (Sparks; par. 0076).

KK. As per claim 45, Sparks discloses the system of claim 41 further including a journaling application transferring orders to the logistics system (Sparks; par. 0076).

LL. As per claim 46, Sparks discloses the system of claim 41 further including an inventory inquiry application communicating with the logistics system (Sparks; par. 0037).

MM. As per claim 47, Sparks discloses the system of claim 41 wherein the logistics system includes an interface application to a commercial shipper (Sparks; par. 0039).

NN. As per claim 48, Sparks discloses the system of claim 41 further including a device return verification application, communicating with the logistics system (Sparks; par. 0059).

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OO. As per claim 49, Sparks discloses the system of claim 41 further including a data extraction application (Sparks; abstract and par. 0016)

PP. As per claim 50, Sparks discloses the system of claim 41 further including a data report generator (Sparks; par. 0018).

QQ. As per claim 52, Sparks discloses the method of claim 51 wherein said steps (c) and (d) are performed sequentially (Sparks; par. 0087).

RR. As per claim 53, Sparks discloses the method of claim 51 wherein said step (d) is performed prior to said step (c) (Sparks; par. 0087).

SS. As per claim 54, Sparks discloses the method of claim 51 wherein said step (c) is performed via said network (Sparks; par. 0090).

TT. As per claim 55, Sparks discloses the method of claim 51 wherein said step (c) is performed via a modem (Sparks; par. 0018).

Examiner considers that since the system disclosed by Sparks includes a modem since it includes communication types such as phone, fax, and e-mail and online.

UU. As per claim 56, Sparks discloses the method of claim 51 wherein said step (c) is performed via a wireless communications link (Sparks; par. 0039).

VV. As per claim 57, Sparks discloses the method of claim 51 wherein said communications network is at least partially a public network (Sparks; par. 0039) and said steps (a) and (c) are performed via a secure link through said network (Sparks; par. 0071).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7, 8, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (U.S. Patent Publication No. 2001/0037215) in view of Snell (U.S. Patent No. 5,722,999).

A. As per claims 7 and 23, Sparks discloses the method of claims 1 and 20.

Sparks fails to expressly teach to provide and record an id (or identification) number for the medical test device, per se, since it appears that Sparks is more directed to provide information and medical device to the patient. However, this feature is well known in the art, as evidenced by Snell.

In particular, Snell discloses a system and method for storing and displaying historical medical data measured by an implantable medical device, wherein unique identifier code is stored in the program memory area (Snell; col. 4, lines 21-23 and 27-29 and col.7, lines 38-41).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within the stored unique identifier number

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taught by Snell with the motivation of the identifier code identifies the implanted or distributed medical device as a device implanted in or distributed to a particular patient (Snell; col. 7, lines 41-42).

B. As per claims 8 and 24, Sparks discloses the method of claims 1 and 20 wherein said step (a) comprises:

(a1) authorizing a requestor to make a request to transmit the test device to the patient (Sparks; paragraph 42);

(a2) accepting a request from the requestor to transmit the test device to the patient (Sparks; paragraph 42);

(a4) communicating with a logistics system or a carrier to transport the device to the patient (Sparks; paragraph 62).

Sparks fails to expressly teach recording an id number for the medical test device, per se, since it appears that Sparks is more directed to provide information and medical device to the patient. However, this feature is well known in the art, as evidenced by Snell.

In particular, Snell discloses a system and method for storing and displaying historical medical data measured by an implantable medical device, wherein unique identifier code is stored in the program memory area (Snell; col.7, lines 38-41).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system

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disclosed by Sparks within the stored unique identifier number taught by Snell with the motivation of the identifier code identifies the implanted or distributed medical device as a device implanted in or distributed to a particular patient (Snell; col. 7, lines 41-42).

7. Claims 25, 36 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (U.S. Patent Publication No. 2001/0037215) in view of applicant's admitted prior art.

A. As per claim 25, sparks discloses the method of claim 20 further including the step of: (d) tracking the time following completion of said step (a) and initiating step (b) within a fixed time period.

Sparks fails to expressly teach to track the time between providing and collecting the medical device, per se, since it appears that Sparks is more directed to provide information and medical device to the patient.

However, this feature is well known in the prior art admitted by the applicant.

In particular, applicant's prior arts U.S. Patent No's 5,797,852 and 5,844,996 disclose devices to provide feedback to physicians following a period of in-home testing by a patient, wherein the patient carries the device home for a one-night test.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within the tracking the time between providing and collecting the

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test with the motivation of the providing feedback to physicians following a period of in-home testing by a patient. (Applicant's specifications; page 3, lines 7-9).

B. As per claims 36 and 51, Sparks discloses a method for conducting a medical test for an authorized physician (Sparks; paragraph 3), comprising:

- (a) collecting an order for a device (Sparks; paragraph 16);
- (b) transmitting a medical test device to a user (Sparks; paragraph 3);
- (c) extracting test results from the test device;
- (d) retrieving the test device from the user subsequent to the user inputting test results into the device; and
- (e) distributing test results to authorized recipients (Sparks; paragraph 38).

Sparks fails to expressly teach to extract the test results from the medical device and also retrieving the test device from the user, per se, since it appears that Sparks is more directed to obtain the results from the patient. However, this feature is well known in the prior art admitted by the applicant.

In particular, applicant's prior arts U.S. Patent No's 5,797,852 and 5,844,996 disclose devices to provide feedback to physicians following a period of in-home testing by a patient, wherein the patient carries the device to the physician, who extracts data from the device.

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It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within the extracting the results from the device with the motivation of the providing feedback to physicians following a period of in-home testing by a patient. (Applicant's specifications; page 3, lines 7-9).

8. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sparks (U.S. Patent Publication No. 2001/0037215) in view of Kulkarni (U.S. Patent Publication No. 2001/0032098).

A. As per claim 41, Sparks discloses a system for providing a test system to a patient, comprising:

- i. an interface server including an ordering interface coupled to a communications network accessible by a plurality of computers (Sparks; paragraph 18);
- ii. a database server coupled to the interface server (Sparks; paragraph 65);
- iii. a logistics system transmitting a medical test to a patient at the direction of a physician accessing the ordering system via the interface server and retrieving the test from the patient upon completion of the test (Sparks; paragraph 37); and
- iv. a data transfer system, collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient.

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Sparks fails to expressly teach a data transfer system, collecting test results from the medical test and distributing results via a secure mechanism to an authorized recipient, per se, since it appears that Sparks is more directed to obtain the results from the patient. However, this feature is well known in the art, as evidenced by Kulkarni.

In particular, Kulkarni discloses an internet ready medical device, wherein a control box can be modified to send the readings over the internet (Kulkarni; paragraph 36).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have combined distribution system disclosed by Sparks within sending the readings over the internet taught by Kulkarni with the motivation of to determine the appropriate action to be taken depend on the reading (Kulkarni; paragraph 36).

Response to Arguments

9. Applicant's arguments with respect to claims 1-57 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. "Electronic system for tracking and monitoring articles to be sterilized and associated method" 2003/0170901, "Personalized health care provider directory" 6,014,629, "Method and apparatus for electronically accessing and distributing personal health care information and services in hospitals and homes" 5,867,821, "Automated system for identifying authorized system users" 5,689,247, "Delivery of medical services using electronic data communications" 5,619,991, "Portable non-invasive testing apparatus" 5,257,627, "Device for obtaining, transporting and using a liquid specimen" 4,596,157.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-272-8295. The examiner can normally be reached on 8-4:30.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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06/19/2006


C. LUKE GILLIGAN
PATENT EXAMINER